

### **Remarks**

Claims 1, 3-5 and 8-10 are pending in this application. All claims have been rejected.

### **Formal Matters**

#### **I. Compliance With 37 CFR 1.821 – 1.825**

The Examiner noted that the specification did not comply with the sequence listing rules under 37 CFR 1.821 – 1.825. With the foregoing amendments to the specification, Applicant contends that the sequence disclosures in the application have been brought into conformance with 37 CFR 1.821 – 1.825.

#### **II. Objections to the Claims**

The Examiner objected to Claim 10 under 37 CFR 1.75(c) as being improperly dependant upon Claim 8 since the claim contains no further limitation. Applicant has now amended Claim 10 to depend on Claim 1, and to particularly point out that the pentapeptide is Val-Pro-Gly-Val-Gly (SEQ. ID. NO:1).

The Examiner also objected to Claims 4 and 5. The foregoing amendments to the claims have added the comma after “Claim 3”, as required by the Examiner.

### **Amendments to the Specification**

By the foregoing amendment, Applicant has amended sections of the specification by moving the sequences of paragraphs and by adding verbatim text from articles cited in the specification and incorporated by reference. Applicant submits that the verbatim addition of such text do not constitute new matter. *See* MPEP § 2163.07(b).

Specifically, Applicant has inserted the text of previously paragraph 0010.4 to paragraph 0010.2. Additional text from Urry et al., “Protein-Based Polymeric Materials

(Synthesis and Properties), Polymeric Materials Encyclopedia, vol. 9 (1996) was included to clarify the construction of these synthetic sequences. Text from Zhang, Xiaorong, Urry, Dan; Daniell, H. "Expression of an environmentally friendly synthetic protein-base polymer gene in transgenic tobacco plants" Plant Cell Reports (1996) 16: 174 – 179 has been added to paragraph 0010.4 to clarify the construction of a (gly-val-gly-val-pro)<sub>121</sub> polymer.

Newly added paragraphs 0010.4.1 to 0010.4.3 consist of text derived verbatim from McPherson, David T., et al. "Production and Purification of a Recombinant Elastomeric Polypeptide, G-(VPGVG)<sub>19</sub>-VPGV, from *Escherichia coli*", Biotechnol. Prog. 1992, 8, 347-352. From Trolinder, Norma L. and Goodin, J.R. "Somatic embryogenesis and plant regeneration in cotton (*Gossypium hirsutum* L.)" Plant Cell Reports (1987) 6:231-234, Applicant has added the text identifying the suitable cultivars for regeneration after agrobacterium-mediated transformation to paragraph 0018.

### **Acknowledgement**

Applicant acknowledges that claims 1, 3-5 and 8-10 are free of prior art.

### **Substantive Rejections**

#### **I. Rejection under 35 USC § 112, first paragraph (Lack of Enablement)**

Applicant acknowledges with thanks the Examiner's withdrawal of the plasmid deposit requirement referenced in the last Office Action.

Nevertheless, the Examiner has maintained the rejection of the pending claims under 35 USC § 112, first paragraph. The Examiner stated that:

The claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and / or use the invention. . . . Given the claim breath and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate

nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once and cotton plants comprising them.

Office Action, pg. 3. The Examiner states that the specification “does not teach how to distinguish synthetic coding sequences from non-synthetic ones, and does not teach any pentapeptides to be other than GVGVP or VPGVG.” Office Action, page 4. The Examiner further states that “the instant specification fails to provide guidance for nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once or nucleic acids encoding 20-251 repeats of GVGVP.” *Id.*

Applicant respectfully disagrees. Applicant submits that those skilled in the art will understand what is meant by synthetic and non-synthetic without issue. According to the Merriam-Webster dictionary, “synthetic” means “of, relating to, or produced by chemical or biochemical synthesis; especially: produced artificially.” *See* Exhibit A. Applicant asserts that this plain meaning of the word applies to the instant specification and that no other differentiation between “synthetic” and “non-synthetic” is necessary. Moreover, using synthetic oligonucleotides to construct genes is a method well known to one skilled in the art. *See* McPherson, D. et al. “Production and Purification of a Recombinant Elastomeric Polypeptide, G-(VPGVG)<sub>19</sub>-VPGV, from *Escherichia coli*”, *Biotechnol. Prog.* 1992, 8, 347-352 and Zhang, Xiaorong, et al.. “Expression of an environmentally friendly synthetic protein-base polymer gene in transgenic tobacco plants” *Plant Cell Reports* (1996) 16: 174 – 179. The availability of these publications show that those skilled in the art, at the time of this application’s filing, were familiar with the construction and expression of synthetic polymers containing multiple pentapeptide repeats.

Applicant also respectfully disagrees with the statement that no guidance is given in the specification for nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once or nucleic acids encoding 20-251 repeats of GVGVP. The specification provides guidance for a nucleic acid encoding GVGVP-GVGFP-GEGFP-GVGVP-GVGFP-GFGFP, which comprises two GVGVP pentapeptides. Moreover, the specification teaches that polypeptides which comprise 121 repeats of GVGVP are well known in the art. Specifically, paragraph 0010 of the specification references the publications that report expression of genes encoding the 121-mer in different systems, which content were incorporated into the specification by reference. By this amendment, Applicant has further clarified the making of a pentapeptide repeat through inserted text from cited references. For example, the elastomeric pentapeptide (gly-val-gly-val-pro)<sub>10</sub> may be constructed by using polymerase chain reaction.

Further examples are detailed in the specification. Line 2 of paragraph 0010 references “Hyperexpression of a Synthetic Protein-Based Polymer Gene,” which was published in *Methods in Molecular Biology* in 1997 by Applicant’s research group. This publication provides step-by-step instructions and detailed discussions on methods and materials to construct a basic polymer building block of (GVGVP)<sub>10</sub> and thereafter to construct the (GVGVP)<sub>121</sub> polymer by ligase concatenation of the basic polymer building block. In another example, “Expression of an environmentally friendly synthetic protein-based polymer gene in transgenic tobacco plant” published in 1996 in *Plant Cell Reports* and cited on line 3 of paragraph 0010, similarly provides guidance on constructing the gene for (GVGVP)<sub>121</sub>, the methods of transformation and analysis. All articles cited in paragraph 0010 was incorporated by reference and made a part of the specification. Applicant therefore asserts that the specification provides

ample guidance to those skilled in the art how to construct and express pentapeptides, such as GVGVP, which contain at least one repeat and up to 30 – 251 repeats.

Applicant thus respectfully submit that the specification, as amended, provides ample guidance for nucleic acids that comprise a synthetic coding sequence encoding any pentapeptide that is repeated at least once or nucleic acids encoding 20-251 repeats of GVGVP.

The Examiner also based her rejection of the claims because the specification did not teach a viable method of transformation. Specifically, the specification disclosed that the bombardment transformation method was identified is not suitable for the university research setting, and the agrobacterium-mediated transformation was not cultivar-independent. Applicant has now identified the cultivar of cotton that are useful for regeneration after agrobacterium-mediated transformation. This information was set forth in Trolinder and Goodin (1986), which had been incorporated by reference into the specification. No new matter was added. In view of this, the specification, as amended, teaches a viable method of cotton transformation.

The amended specification provides guidance to one skilled in the art to construct the synthetic polypeptide containing any number of repeats of the base GVGVP sequence and a method of transformation. Accordingly, Applicant submits that the specification is enabling, and respectfully requests that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn.

II. Rejection under 35 USC § 112, first paragraph (Written Description)

The Examiner has rejected the pending claims as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed.

By the foregoing amendment, the Applicant has provided additional guidance on how to make the pentapeptide repeats. As urged above, those skilled in the art knew well the differences between a synthetic sequences and non-synthetic (or those isolated from nature) sequences and how to make them. In light of the amendments to the specification and the arguments above, Applicant respectfully requests that the Examiner withdraw her Written Description rejections of the pending claims.

III. Rejection under 35 USC § 112, first paragraph (New Matter)

The Examiner regards the phrase “[t]he transgenic cotton plant of claim 1, wherein said gene encodes between 20-251 repeats of the amino acid sequence Gly-Val-Gly-Val-Pro (SEQ ID NO:2)” as unsupported new matter. Applicant respectfully traverses.

Applicant again respectfully calls the Examiner’s attention to page 2 of the Provisional Application Serial No. 60/074,997 which is here incorporated in full, as well as paragraph 0010 of the specification. There is identified not only a large polypeptide containing 251 repeats of Gly-Val-Gly-Val-Pro, but a “small, 100 amino acid polypeptide (GVGVP)<sub>20</sub>” as well. Further, a polypeptide of 121 repeats of Gly-Val-Gly-Val-Pro is likewise disclosed. Those skilled in the art will readily understand the range of possible repeats to be between 20 and 251. Applicant therefore submits that the objected-to phrase is fully supported by the specification and respectfully requests that the rejection be withdrawn.

VI. Rejections under 35 U.S.C. §112, second paragraph


The pending claims are rejected on the basis of indefiniteness. Applicant thanks the Examiner for her helpful suggestions regarding word choice and ordering. By the foregoing amendments, Applicant submits that the indefiniteness of the claims have been cured.

**Conclusion**

Applicant believes that this amendment has addressed all outstanding issues such that this patent application is in condition for allowance. As no issues remain outstanding, early allowance of the application is respectfully requested.

Respectfully submitted,

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CERTIFICATE OF MAILING

I HEREBY CERTIFY that this RESPONSE TO FINAL OFFICE ACTION is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Mail Stop Missing Parts, Alexandria, Virginia 22313-1450 1st day of June, 2005.

  
Alicia Hoffman